K043483

JAN 2 8 2005

E. Administrative Information

E.1 510(k) Summary of Safety and Effectiveness

E.1.1 Company Identification

SOHARD AG
Wuerzburger Str. 197
90766 Fuerth
Germany
Tel.: 011-49911-97341-0
Fax.: 011-49911-97341-10

E.1.2 Official Correspondent

Ralph Loos, RA/QM
Wuerzburger Str. 197
90766 Fuerth
Germany
Tel.: 011-49911-97341-553
Fax.: 011-49911-97341-510

E.1.3 Date of Submission

11/19/2004

E.1.4 Device Name

Trade name:	RADIN
Release Version:	3.0
Common name:	RADIN
Classification Name:	Picture Archiving and Communications System
Reference:	per 21 CFR 892.2050
Class:	II
Review Panel:	Radiology
Product Classification:	90 LLZ, Picture Archiving and Communications System

Guidance document: Guidance for the submission of premarket notifications for medical image management systems (issued on july 27, 2000)

E.1.5 Substantial Equivalence

The RADIN Software is substantially equivalent, in the opinion of SOHARD AG, to Thinking Systems ThinkingNet (K010271, Class II).

E.1.6 Device Description

RADIN 3.0 is a system to distribute medical images and reports within and outside of health care environments. It is available as a stand-alone software package.

RADIN consists of the following set of software modules:

- **RADIN.online** is the main component, its scalable server architecture provides high availability of medical images
- **RADIN.web** provides standardized internet technology for web-based image communication
- **RADIN.archive** enhances RADIN.online with long term archiving on media (e.g. harddisk, jukebox)

RADIN offers three types of clients:

- **RADIN.Classic Client** provides the basic viewing and workflow features, e.g. support of CR, CT, MR and NM modalities, support of greyscale, color and multiframe images.
- **RADIN.Expert Client** additionally offers gamma adjustment, display of scoutlines and image export.
- **RADIN.Expert dual monitor Client** supports dual monitor operation

RADIN requires standard PC-Hardware, recommendations are made within the labeling.

E.1.7 Intended Use

RADIN 3.0 is a system to distribute medical images and reports within and outside of health care environments.

The **RADIN Server** receives image data in DICOM format via the hospital network. This provides universal connections to archives, modalities and workstations. The modalities that are supported by RADIN are listed in the DICOM Conformance Statement [1].

For data transfer to clients you have to activate strong SSL data encryption to make the transfer secure.

Data that are stored on the RADIN server can be accessed simultaneously by many viewing stations within a healthcare enterprise or from elsewhere outside. The image data transfer is done in DICOM format via the Intranet or the Internet, for example to stations located in a doctor's office, throughout hospitals or a physician's home.

Integration with other hospital information systems (HIS, RIS, CIS) is possible via a special OEM interface.

Images can be viewed directly within a web browser (Internet Explorer). The system offers simple functions for image manipulation and measurements. Reports can be viewed together with the images on one page.

RADIN can support physicians and/or their medical staff with the diagnosis. In that case the user is responsible for all suitable hardware being used in proper working conditions. The final decision regarding diagnoses, however, lies with the doctors and/or their medical staff in their very own responsibility.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA (concerning only the USA).

RADIN offers an archiving option for long-term storage of image data. Only the data consistency on archive media is guaranteed, the system provider has to take own appropriate means (e.g. redundancy) for safety against data loss caused by media destruction. Without the archiving option, the RADIN System features no components for long-term data archiving. Additional archiving on film or in digital form is therefore necessary.

RADIN provides three types of clients:

RADIN.Classic	for basic functionality
RADIN.Expert	for full functionality
RADIN.Expert Dual Monitor	with RADIN.Expert functionality and support of two monitors

All text and messages displayed in the image viewer can be viewed in either:

German

English

French

Spanish

Italian

Portuguese

The Online Help for the image viewer is available in German and English. The text of the administration pages and the Online Help of the administration pages are available in English only.

To guarantee flawless operation of the RADIN system, no additional 3rd party software may be installed on RADIN server. Furthermore, no part of the RADIN product may be manipulated in any way.

If the system is configured to use only patient ID for matching of patient data, the system provider has to make sure that each patient ID is unique for the whole system. Therefore, all interfaces that can deliver images into the system have to be considered - especially interfaces to external institutions.

E.1.8 Software Development

SOHARD AG certifies, that the RADIN software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

All employees receive the appropriate quality system training.

The SOHARD Quality System is in compliance with the following voluntary and mandatory standards and regulations:

Standard/Regulation	Title
21 CFR 820	Quality Systems Regulation
ISO 9001:2000	Quality Management Systems – Requirements
ISO 13485:2000	Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001
93/42/EEC	Medical Device Directive
(IEC) 60601-1-4	International Electrotechnical Commission

E.1.9 Substantial Equivalence Comparison Chart

RADIN has equivalent Intended use and technological characteristics as the predicate device and therefore raises no new safety or effectiveness issues.

Product	RADIN	Thinking Net
General		
Networking	TCP/IP	TCP/IP
Image Acquisition/Communication	DICOM Compliant	DICOM Compliant
Image file formats	DICOM 3.0	DICOM 3.0 Interfile 3.3
Imaging modalities	Multi Modality	Multi Modality
Platform	PC	PC
Operating System	Windows	Windows
Standard Microsoft Technology	Yes	Yes
DICOM 3.0 Compliant	Yes	Yes
Patient Demographics	Yes	Yes
DICOM Storage SCP	Yes	Yes
DICOM Storage SCU	Yes	Yes
DICOM Query/Retrieve SCU/SCP	Yes	Yes
HIPAA compliant	Yes	Yes
	RADIN.Online	
Scalability	1 to several 500 users	yes
Data Compression		
Original Format	Yes	Yes
JPEG Lossless	Yes	Yes
JPEG Lossy	Yes (5-100%)	Yes
Wavelet	Yes (5-100%)	No
Storage Space Management		
Intelligent storage management	Yes	Yes

Product	RADIN	Thinking Net
DICOM Network		
DICOM Conformance	DICOM 3.0	DICOM 3.0
Hardware and Software Requirements		
Hardware	PC Pentium III, min 500MHz 512 MB RAM 20 GB Harddisk	OTS Hardware according to specified minimum hardware requirements
Software	Windows 2000 Server Internet Explorer 6	Windows 2000 Server
	RADIN.Web	
Security Features		
User authentication	yes	yes
Secure data transmission	SSL encryption (optional: VPN encryption)	VPN encryption
User Management		
User Account	Yes	Yes
User groups	Yes	Yes
User Levels	Yes	Yes
Workflow Features		
DICOM report interface	Yes	Unknown
File based report interface	Yes	Unknown
URL interface for OEM integration	Yes	Unknown
Creation of patient media (CD, DVD) according to DICOM standard	Yes	Yes
Hardware and Software Requirements		
Hardware	Pentium 2 GHz 512 MB RAM 50-100 GB Harddisk	OTS Hardware according to specified minimum hardware requirements
Software	Windows 2000 Server Internet Explorer 6	Windows 2000 Server
	RADIN.Archive	
Storage Modules		
DVD-R Jukebox	Yes	Yes
Harddisk RAID	Yes	Yes
Data Security		
Data verification on media	Yes	Unknown
Manipulation detection	Yes	Unknown
Database consistency check	Yes	Unknown
Hardware and Software Requirements		

Product	RADIN	Thinking Net
Hardware	Pentium 2 GHz 512 MB RAM 50-100 GB Harddisk	OTS Hardware according to specified minimum hardware requirements
Software	Windows 2000 Server Internet Explorer 6	Windows 2000 Server
	RADIN.Classic Clients	
Key Features		
Full DICOM images on clients	Yes	Yes
No Software Installation, just Internet Explorer needed	Yes	Yes
Supported Modalities	CR, CT, DR, DS, DX, ES, GM, IO, MG, MR, NM, PT, OT, RF, RT, US, XA, XC	CR, CT, DR, MRI, MRA, US, PET
Supported Image Types		
Greyscale	Yes	Yes
Color	Yes	Yes
Multiframe	Yes	Yes
Image Manipulation Functions		
Zoom	Yes	Yes
Quick Zoom	Yes	Yes
Magnifying glass	Yes	Yes
Pan	Yes	Yes
Window leveling	Yes	Yes
Edge enhancement	Yes	Yes
Grayscale inversion	Yes	Yes
Rotating, flipping	Yes	Yes
MPR, MIP	No	Yes
Measurement Functions		
Distance	Yes	Yes
Angulation	Yes	Yes
Area	No	Yes
Perimeter	No	Yes
Greyscale densitiy (probe)	Yes	No
Manual distance calibration	Yes	No
Cine Mode	Yes	Yes
Workflow features		
Database Filters	Yes	Yes
DICOM query/retrieve from archives and workstations	Yes	Yes

Product	RADIN	Thinking Net
Change user and group assignment of patients	Yes	Yes
Multiple series loading	Yes	Yes
Preloading of images to the client	Yes	Yes
Study availability status	Yes	Yes
Display of images together with reports	Yes	Yes
Easy integration with RIS/HIS systems	Yes	Yes
Windows Copy and Print Functions	Yes	Yes
Hardware and Software Requirements		
Hardware	Pentium III 500 MHz, (Pentium IV 2 GHz recommended) 128 MB RAM (512 MB recommended) Standard PC graphics card, 1024 * 768 minimum resolution 2 GB Harddisk Network or telephone adapter	OTS Hardware according to specified minimum hardware requirements
Software	MSWindows NT4.0, 98, 2000 or XP Internet Explorer 5.5 or 6	Microsoft Windows OS, Internet Explorer
Additional Features		
Dual Monitor Support	Yes	No

E.1.10 Safety and Effectiveness

E.1.10.1 General Safety and Effectiveness Concerns

RADIN is a medical device that is to be used by trained health care professionals who are responsible for the correct and accurate use of medical images e.g. as a means for providing diagnosis.

The device labeling contains instructions for use and the intended use/indications for use. Warnings, faults etc are explained in the users manual.

Images that are compressed are properly identified in the image information as being compressed as specified by the DICOM standard. This compression identification remains with the image for the entire life of the image.

E.1.10.2 Validation and Effectiveness

The RADIN risk analysis has been performed to identify all potential safety or health hazards during system operation. The hazards are controlled by a risk management plan, including hazard analysis, verification and validation tests (according to our software development process) and evaluations by hospitals.

According to our risk analysis and risk management there are no software components within the RADIN Software, whose failure or latent design flaw would be expected to result in death or injury to a patient.

Requirement tracing covering specification, design, implementation and verification/validation ensures the fulfillment of all phase requirements, EHR and DMR ensures direct access to all documents.

Integration test plan defines full testing at integration and system testing level. According to this test plan integration and system testing including full testing of hazard mitigation has been performed.

Decision Reviews at the conclusion of each software development phase ensure the fulfillment of the phase results and the validity of the Intended Use and the risk analysis.

Testing is an integral part of our Software Design Process.

E.1.10.3 Substantial Equivalence

Any differences between the RADIN Software and the substantially equivalent device have no significant influence on safety and effectiveness.

E.1.10.4 Technological characteristics

RADIN is a stand-alone software package used on general purpose hardware, as long as the minimum hardware requirements specified in the manuals are met.

It is based upon standard Microsoft™ technology.

The device does not contact the patient, nor does it control any life sustaining devices.

A physician, providing ample opportunity for competent human intervention interprets images and information delivered by RADIN.

E.1.10.5 Conclusion

We believe, that the 510(k) premarket notification contains adequate information and data to enable FDA to determine substantial equivalence to the predicate device.

RADIN has been and will be manufactured in accordance with the mandatory and voluntary standards listed in this submission.

This submission contains the result of the hazard analysis and all potential hazards have been classified as minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

SoHard, AG
% Ms. Joan C. Mazur
Vice President
Integrated Modular Systems, Inc.
2500 W. Township Line Road
P.O. Box 616
HAVERTOWN PA 19083

Re: K043483
Trade/Device Name: RADIN V3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 14, 2004
Received: December 17, 2004

Dear Ms. Mazur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

D. Statement of Indications for Use

510(k) Number (if known): K043483

Device Name: RADIN

Indications for Use:

RADIN can be used whenever digital images and associated data acquired or generated by different third party modalities have to be accepted, displayed, transmitted, stored, distributed, processed and archived in order to be available for professional health care personnel. RADIN is not intended to assist the healthcare personnel in diagnosis. RADIN can be used together with appropriate and proper installed computer platforms according to the recommendations made in the labeling.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Typical users are trained healthcare professionals including but not limited to physicians, licenced practitioners, nurses.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043483

Page __ of ___